DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Carl Zeiss Meditec AG
c/o Ms. Mandy Ambrecht
Carl Zeiss Meditec, Inc.
Staff Regulatory Affairs Specialist
5160 Hacienda Drive
Dublin, CA 94568

November 18, 2014

Re: K141844
Trade/Device Name: RESCAN 700
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: October 16, 2014
Received: October 17, 2014

Dear Ms. Ambrecht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance. You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141844

Device Name
RESCAN 700

Indications for Use *(Describe)*

RESCAN 700 provides non-contact, high resolution, optical coherence tomographic (OCT) and biomicroscopic imaging of the anterior and posterior segment of the eye via an ophthalmic surgical microscope. The RESCAN 700 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, macula, and optic disc, as well as imaging of anterior ocular structures, including the cornea, lens and anterior chamber angle.

RESCAN 700 uses an assistance system (CALLISTO Eye) that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The assistance system allows the remote control of RESCAN 700.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5. 510(K) SUMMARY

5. 510(k) Summary

510(k) SUMMARY
(per 21 CFR §807.92)

RESCAN 700

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany + 49 736420-9626 (phone) + 49 736420-2035 (fax) Establishment Registration Number: 9615030
Contact Person:	Mandy Ambrecht Staff Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 (925) 557-4561 Phone (925) 557-4259 Fax E-mail: mandy.ambrecht@zeiss.com
Date prepared:	November 17, 2014
Trade/Proprietary Name:	RESCAN 700
Common Name:	Tomography, Optical coherence Picture Archiving and Communication System Surgical microscope and accessories
Classification Name:	Ophthalmoscope System, Image Management, Ophthalmic Microscope, Surgical
Product Code and Class:	OBO - Class II NFJ EPT
Classification Number:	21 CFR 886.1570

SECTION 5. 510(K) SUMMARY

PREDICATE DEVICE:

Company:	Carl Zeiss Meditec AG
Device	CIRRUS photo (K112184)
Company:	Carl Zeiss Meditec AG
Device:	CALLISTO eye (K123464)

INDICATIONS FOR USE

RESCAN 700 provides non-contact, high resolution, optical coherence tomographic (OCT) and biomicroscopic imaging of the anterior and posterior segment of the eye via an ophthalmic surgical microscope. The RESCAN 700 is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging of posterior ocular structures, including retina, macula, and optic disc, as well as imaging of anterior ocular structures, including the cornea, lens and anterior chamber angle.

RESCAN 700 uses an assistance system (CALLISTO eye) that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The assistance system allows the remote control of RESCAN 700.

DEVICE DESCRIPTION

RESCAN 700 brings Spectral Domain OCT technology to the Zeiss OPMI Lumera 700 ophthalmic surgical microscope. Used in conjunction with software version 3.2 of an assistance system, CALLISTO eye, OCT images taken intra operatively are presented on the monitor and may also be seen within the surgeon's oculars using the OPMI Lumera 700's integrated data injection system (IDIS). OCT images may be stored for subsequent retrieval using CALLISTO eye's data management system. RESCAN 700 can be controlled via the touch panel of the assistance system or via the foot control panel of an ophthalmic surgical microscope.

RESCAN 700 is used with CALLISTO eye software version 3.2. A table comparing the features in each CALLISTO eye software version is provided on the following page for clarification.

SUBSTANTIAL EQUIVALENCE

RESCAN 700 is substantially equivalent to the CIRRUS photo (K112184) with regards to indications for use. RESCAN 700 and CIRRUS photo are both intended to provide OCT images of the anterior and posterior segment of the eye. RESCAN 700 is used with CALLISTO eye

SECTION 5. 510(K) SUMMARY

software version 3.2. Both the proposed product, CALLISTO eye, and the predicate device, CALLISTO eye, provide non-diagnostic video documentation and image capture for ophthalmic surgeries and allow remote control of the surgical microscope.

Functions	**CALLISTO eye SW Version 3.0**	**CALLISTO eye SW Version 3.1**	**CALLISTO eye SW Version 3.2**
User Management	x	x	x
Patient management	x	x	x
Surgery (video) recording	x	x	x
Live video	x	x	x
Control center	x	x	x
Ophthalmic surgical microscope remote control (OPMI Lumera 700)	x	x	x
Network connectivity	x	x	x
Import/Export of data via USB stick	x	x	x
Assistance functionalities Z ALIGN, Rhexis, LRI/Incision, Reference and KTrack	x	x	Not available
Control of the RESCAN 700 (OCT Camera) connected to the OPMI Lumera 700			x
Visualization of OCT data			x
Capture and Review of OCT datasets (images and scans)			x

PERFORMANCE DATA

RESCAN 700 was designed and tested to the applicable standards for electrical and optical safety and verified to established standards. Performance testing was conducted on RESCAN 700 and it was found to perform as intended. Each function and/or feature was tested by means of an appropriate test case or test specification.

Testing of the device with RESCAN 700, OPMI Lumera 700 and CALLISTO eye has been conducted to demonstrate conformance to the third edition of 60601-1 in addition to the IEC 60601-1-2 standard for electromagnetic compatibility. In addition to systems testing, software verification activities completed were divided into three phases:

- Tests accompanying development (including code inspections)
- Integration test phase – stabilization phase
- System verification

Validation and usability testing was conducted with RESCAN 700 in conjunction with CALLISTO eye to ensure that the medical device meets the product and user requirements and to support a determination of substantial equivalence to the predicate devices.

SECTION 5. 510(K) SUMMARY

Verification and validation activities were successfully completed and prove that RESCAN 700 and CALLISTO eye meet their requirements and perform as intended.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on RESCAN 700 and CALLISTO eye to ensure that the device is as safe and effective as the predicate devices.